

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and
BOSTON SCIENTIFIC SCIMED, INC.,

Plaintiffs,

v.

JOHNSON & JOHNSON, INC. and
CORDIS CORPORATION,

Defendants.

Civil Action No. 07-333-SLR

JURY TRIAL DEMANDED

**AMENDED COMPLAINT FOR DECLARATORY JUDGMENT
OF PATENT INVALIDITY, UNENFORCEABILITY AND NONINFRINGEMENT**

Plaintiffs Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively "BSC"), through its attorneys, bring this amended complaint against Defendants Johnson & Johnson, Inc. and Cordis Corporation (collectively "J&J") and requests a jury trial on all issues so triable. BSC alleges as follows, upon knowledge with respect to itself and its own acts, and upon information and belief as to the circumstances and facts of others:

NATURE OF THE ACTION

1. This is an action for a declaratory judgment that United States Patent No. 7,217,286 entitled "Local Delivery of Rapamycin for Treatment of Proliferative Sequelae Associated With PTCA Procedures, Including Delivery Using a Modified Stent" ("the Falotico '286 patent") is invalid, unenforceable and not infringed by BSC. The Falotico '286 patent is attached as Exhibit A.

THE PARTIES

2. Plaintiff Boston Scientific Corporation is a corporation organized under the laws of the State of Delaware, having its principal place of business at One Boston Scientific Plaza, Natick, Massachusetts 01760.

3. Plaintiff Boston Scientific Scimed, Inc. is a corporation organized under the laws of the State of Minnesota, having its principle place of business at One Scimed Place, Maple Grove, MN 55311-1566.

4. Upon information and belief, Defendant Johnson & Johnson, Inc. is a corporation organized under the laws of the State of New Jersey and has a principal place of business at 1 Johnson and Johnson Plaza, New Brunswick, New Jersey.

5. Upon information and belief, Defendant Cordis Corporation ("Cordis") is a corporation organized under the laws of the State of Florida and has a principal place of business in Miami Lakes, Florida. Cordis is a subsidiary of Johnson & Johnson, Inc.

JURISDICTION AND VENUE

6. This action arises under the Patent Laws of the United States (35 U.S.C. § 1, *et seq.*).

7. This Court has jurisdiction over the subject matter of all causes of action herein pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

8. On information and belief, J&J has systematic and continuous contacts in this judicial district.

9. On information and belief, J&J regularly avails itself of the benefits of this judicial district, including the jurisdiction of the courts.

10. On information and belief, J&J regularly transacts business within this judicial district.

11. On information and belief, J&J regularly sells products in this judicial district. J&J derives substantial revenues from sales in this district.

12. This Court has personal jurisdiction, general and specific, over J&J.

13. Venue in this judicial district is proper pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

BACKGROUND

14. BSC is a world renowned leader in the development of intravascular stents used to treat coronary artery disease.

15. J&J and, in particular, Cordis, directly compete with BSC in the field of intravascular stents used to treat coronary artery disease.

16. J&J has a well-known history of suing competitors, including BSC, in the field of intravascular stents for patent infringement. Within the past several years, J&J and/or Cordis have sued BSC in this Court, alleging patent infringement in cases involving intravascular stents used to treat coronary artery disease. BSC has also brought suits for patent infringement against J&J within this judicial district.

17. Pursuant to an agreement between BSC and Abbott Laboratories ("Abbott"), BSC is presently selling the PROMUS Stent System ("PROMUS") in both the United States and Europe. The PROMUS stent is a private-labeled XienceV Everolimus-Eluting Coronary Stent System ("XIENCE V") which is manufactured for BSC by Abbott. The PROMUS stent is an intravascular stent used to treat coronary artery disease. It advantageously releases a drug

designed to diminish reblocking (restenosis) of the patient's blood vessel into which the stent has been inserted.

18. The PROMUS stent received CE Mark approval in October 2006, which allows BSC to distribute PROMUS in 27 countries of the European Economic Area. Since that time, BSC has been taking title to the PROMUS stent from Abbott in the United States and then exporting those stents to the European market. BSC received approval for its PROMUS stent in the United States on July 2, 2008; and began selling it in the United States shortly thereafter.

19. In 2006, BSC purchased Guidant Corporation ("Guidant"). As part of the agreement governing the Guidant acquisition, Guidant separately sold the rights to its everolimus-eluting stent product to Abbott. BSC separately entered into an agreement with Abbott that permits BSC to sell (under the designation "PROMUS") the everolimus-eluting stents manufactured by Abbott (which Abbott sells on its own as its "XIENCE V" stent).

20. Abbott currently manufactures and sells its own everolimus-eluting stent, the XIENCE V stent, which is the same product as BSC's PROMUS stent.

21. On May 15, 2007, Cordis Corporation filed a patent infringement suit against Abbott in the United States District Court for the District of New Jersey. *See* Exhibit B, the Complaint in Civil Action No. 07-2265-JAP-TJB. Cordis alleges in its May 15 Complaint that Abbott's manufacture and/or use of the XIENCE V stent in the United States infringes the Falotico '286 patent. *Id.*, pp. 3-4. Among other remedies, Cordis seeks a preliminary and permanent injunction prohibiting Abbott from making, using, selling, or offering for sale the XIENCE V stent in the United States. *Id.*, p. 4.

22. Cordis' patent infringement suit, as referenced in paragraph 21, has created a present substantial controversy between J&J and BSC concerning the PROMUS stent. J&J,

through Cordis, has asserted rights under the Falotico '286 patent against the same product as the PROMUS stent, and the alleged infringement of that patent has created apprehension that, if Cordis is successful in its suit, BSC's investment in the PROMUS stent will be harmed.

RELATED CASES PENDING IN THE DISTRICT OF DELAWARE

23. There are currently three, additional declaratory judgment actions on related patents and the Promus stent pending in the District of Delaware; namely Civil Action No. 07-348-SLR, Civil Action No. 07-409-SLR, and Civil Action No. 07-765-SLR.

COUNT I

INVALIDITY AND NONINFRINGEMENT OF U.S. PATENT NO. 7,217,286

24. BSC repeats and realleges each and every allegation contained in paragraphs 1-
Error! Reference source not found. of this Amended Complaint as though fully set forth herein.

25. Each of the claims in the Falotico '286 patent is invalid for failure to comply with one or more of the requirements of Title 35, United States Code, including, but not limited to, 35 U.S.C. §§ 102, 103 and 112.

26. The PROMUS stent does not infringe any valid claim of the Falotico '286 patent.

COUNT II

UNENFORCEABILITY OF U.S. PATENT NO. 7,217,286

27. BSC repeats and realleges each and every allegation contained in paragraphs 1-
Error! Reference source not found.6 of this Amended Complaint as though fully set forth herein.

28. Each of the claims in the Falotico '286 patent is unenforceable due to inequitable conduct before the United States Patent and Trademark Office ("PTO"). Multiple examples of this inequitable conduct are discussed below and BSC believes that additional examples are likely to have evidentiary support after reasonable opportunity for further investigation and discovery.

29. The Falotico '286 patent issued from U.S. Patent Application Serial No. 11/467,035 ("the '035 Application"), which is a continuation of U.S. Patent Application Serial No. 10/951,385 ("the '385 Application"), which is a continuation of U.S. Patent Application Serial No. 10/408,328 ("the '328 Application"), which is a continuation of U.S. Patent Application Serial No. 09/874,117 ("the '117 Application"), which is a continuation of U.S. Patent Application Serial No. 09/061,568 ("the '568 Application"), and additionally claims priority to Provisional Application No. 60/044,692 (the '692 application") filed on April 18, 1997.

30. In prosecuting the application leading to the Falotico '286 patent, the past and present named inventors, their prosecuting attorneys and agents, their assignees and/or others associated with the prosecution of the applications leading to the Falotico '286 patent (collectively, "the Applicants"), were under a duty of candor and good faith to the PTO pursuant to the regulations of the PTO and the law, which included a duty to disclose material information to the PTO

31. The Falotico '286 patent is unenforceable due to inequitable conduct because, among other reasons, the Applicants failed to comply with their duty of candor and good faith to the PTO, including their duty to disclose material information to the PTO.

32. For instance, upon information and belief, with intent to deceive the PTO, the Applicants intentionally and knowingly withheld the following information from the PTO during the pendency of the applications which led to the Falotico '286 patent, which information a reasonable Patent Examiner would have considered relevant, important and/or material to the patentability of the claims then-pending in the applications that led to the Falotico '286 patent as well as the claims that ultimately issued in that patent: (a) despite prosecuting, pursuing and obtaining claims embracing stents having a bioabsorbable polymer coating, the Applicants knew during the prosecution that such bioabsorbable polymers prevented the claimed stents from inhibiting restenosis and/or neointimal proliferation, presented fatal drug loading issues, caused inflammation, and generally did not work in the claimed subject matter and, as such, the Applicants knew that they were not in possession of the claimed subject matter at the time of the alleged invention; (b) the Applicants were aware of the existence of prototype stents in the prior art to the claimed subject matter, including paclitaxel-eluting stents using an EVA polymer coating which Applicants themselves had prepared and tested in animals in connection with Angiotech; (c) prior to filing the first application that led to the Falotico '286 patent, the Applicants conducted no experiments with the polymers listed in the application and recited in the claims as suitable coatings for the claimed stents, but learned during prosecution of the applications leading to that patent that certain preferred emhodiments (e.g., either EVA or PBMA, alone, as the polymer coating) did not work as such a coating, and did not disclose any of that information to the PTO or the fact that a collaborator company developing such stent coatings obtained a patent of its own on polymer coatings that actually did work on the claimed stents; (d) the Applicants were aware of a dispute over the correct inventorship on the applications that led to the Falotico '286 patent during their prosecution, including, but not

limited to, assertions by Wyeth that one or more of its employees should have been named as inventors of the claimed subject matter; (e) the Applicants did not themselves research, develop, create or invent any of the component parts or the whole of the claimed subject matter, including, but not limited to, the drug, polymer coating and/or stent recited in the claims; (f) the language (including "analogs") used to define and claim the subject matter of the alleged invention of the Falotico '286 patent was created by individuals, including attorneys, not named as inventors on the applications that led to the Falotico '286 patent, and was intended to improperly broaden the scope of the pending and issued claims beyond the scope of the subject matter actually in possession of the individuals named as inventors on those applications; and (g) following the filing of the provisional application that led to the Falotico '286 patent and prior to the filing of the first application that led to that patent, the best mode for practicing the alleged invention of the Falotico '286 patent was developed by others not named as inventors on the Falotico '286 patent, was conveyed to those named inventors, and those facts and the best mode itself were then intentionally withheld and concealed from the PTO

33. Additionally, as illustrated by the examples below, the Applicants failed to disclose many highly material patents assigned to Cordis' licensor, Wyeth.

34. As an example of the inequitable conduct before the PTO that renders the Falotico '286 patent unenforceable, as part of the filing and prosecution of the application leading to the Falotico '286 patent, one or more of the Applicants failed to disclose the material reference U.S. Patent No. 5,252,579 ("the '579 patent") to the PTO. Upon information and belief, one or more of the Applicants failed to disclose the 579 patent with the intent to deceive the PTO into granting the Falotico '286 patent.

35. Upon information and belief, a reasonable Patent Examiner would have considered the '579 patent important to the patentability of the claims in the application leading to the Falotico '286 patent.

36. Upon information and belief, one or more of the Applicants knew of the '579 patent and its materiality during prosecution of the application leading to the Falotico '286 patent. For example, upon information and belief, one or more of the Applicants knew of the '579 patent via the on-going licensing relationship between Cordis and the assignee of the '579 patent.

37. Despite having knowledge that the '579 patent was relevant and material to the prosecution of the application leading to the Falotico '286 patent, one or more of the Applicants nevertheless failed to disclose the '579 patent to the PTO during prosecution of that application. This failure to disclose the highly material '579 patent was motivated by, and accomplished with, the intent to deceive the PTO into granting the Falotico '286 patent.

38. As another example of the inequitable conduct before the PTO that renders the Falotico '286 patent unenforceable, as part of the filing and prosecution of the application leading to the Falotico '286 patent, one or more of the Applicants failed to disclose the material reference U.S. Patent No. 5,256,790 ("the '790 patent") to the PTO. Upon information and belief, one or more of the Applicants failed to disclose the '790 patent with the intent to deceive the PTO into granting the Falotico '286 patent.

39. Upon information and belief, a reasonable Patent Examiner would have considered the '790 patent important to the patentability of the claims in the application leading to the Falotico '286 patent.

40. Upon information and belief, one or more of the Applicants knew of the '790 patent and its materiality during prosecution of the application leading to the Falotico '286 patent. For example, upon information and belief, one or more of the Applicants knew of the '790 patent via the on-going licensing relationship between Cordis and the assignee of the '790 patent.

41. Despite having knowledge that the '790 patent was relevant and material to the prosecution of the application leading to the Falotico '286 patent, one or more of the Applicants nevertheless failed to disclose the '790 patent to the PTO during prosecution of that application. This failure to disclose the highly material '790 patent was motivated by, and accomplished with, the intent to deceive the PTO into granting the Falotico '286 patent.

42. As another example of the inequitable conduct before the PTO that renders the Falotico '286 patent unenforceable, as part of the filing and prosecution of the application leading to the Falotico '286 patent, one or more of the Applicants failed to disclose the material reference U.S. Patent No. 5,362,718 ("the '718 patent") to the PTO. Upon information and belief, one or more of the Applicants failed to disclose the '718 patent with the intent to deceive the PTO into granting the Falotico '286 patent.

43. Upon information and belief, a reasonable Patent Examiner would have considered the '718 patent important to the patentability of the claims in the application leading to the Falotico '286 patent.

44. Upon information and belief, one or more of the Applicants knew of the '718 patent and its materiality during prosecution of the application leading to the Falotico '286 patent. For example, upon information and belief, one or more of the Applicants knew of the

'718 patent via the on-going licensing relationship between Cordis and the assignee of the '718 patent.

45. Despite having knowledge that the '718 patent was relevant and material to the prosecution of the application leading to the Falotico '286 patent, one or more of the Applicants nevertheless failed to disclose the '718 patent to the PTO during prosecution of that application. This failure to disclose the highly material '718 patent was motivated by, and accomplished with, the intent to deceive the PTO into granting the Falotico '286 patent.

46. As another example of the inequitable conduct before the PTO that renders the Falotico '286 patent unenforceable, as part of the filing and prosecution of the application leading to the Falotico '286 patent, one or more of the Applicants failed to disclose the material reference U.S. Patent No. 5,391,730 ("the '1730 patent") to the PTO. Upon information and belief, one or more of the Applicants failed to disclose the '1730 patent with the intent to deceive the PTO into granting the Falotico '286 patent.

47. Upon information and belief, a reasonable Patent Examiner would have considered the '1730 patent important to the patentability of the claims in the application leading to the Falotico '286 patent.

48. Upon information and belief, one or more of the Applicants knew of the '1730 patent and its materiality during prosecution of the application leading to the Falotico '286 patent. For example, upon information and belief, one or more of the Applicants knew of the '1730 patent via the on-going licensing relationship between Cordis and the assignee of the '1730 patent.

49. Despite having knowledge that the '1730 patent was relevant and material to the prosecution of the application leading to the Falotico '286 patent, one or more of the Applicants

nevertheless failed to disclose the '1730 patent to the PTO during prosecution of that application. This failure to disclose the highly material '1730 patent was motivated by, and accomplished with, the intent to deceive the PTO into granting the Falotico '286 patent.

50. As another example of the inequitable conduct before the PTO that renders the Falotico '286 patent unenforceable, as part of the filing and prosecution of the application leading to the Falotico '286 patent, one or more of the Applicants failed to disclose the material reference U.S. Patent No. 5,441,977 ("the '977 patent") to the PTO. Upon information and belief, one or more of the Applicants failed to disclose the '977 patent with the intent to deceive the PTO into granting the Falotico '286 patent.

51. Upon information and belief, a reasonable Patent Examiner would have considered the '977 patent important to the patentability of the claims in the application leading to the Falotico '286 patent.

52. Upon information and belief, one or more of the Applicants knew of the '977 patent and its materiality during prosecution of the application leading to the Falotico '286 patent. For example, upon information and belief, one or more of the Applicants knew of the '977 patent via the on-going licensing relationship between Cordis and the assignee of the '977 patent.

53. Despite having knowledge that the '977 patent was relevant and material to the prosecution of the application leading to the Falotico '286 patent, one or more of the Applicants nevertheless failed to disclose the '977 patent to the PTO during prosecution of that application. This failure to disclose the highly material '977 patent was motivated by, and accomplished with, the intent to deceive the PTO into granting the Falotico '286 patent.

54. As another example of the inequitable conduct before the PTO that renders the Falotico '286 patent unenforceable, as part of the filing and prosecution of the application leading to the Falotico '286 patent, one or more of the Applicants failed to disclose the material reference U.S. Patent No. 5,563,145 ("the '145 patent") to the PTO. Upon information and belief, one or more of the Applicants failed to disclose the '145 patent with the intent to deceive the PTO into granting the Falotico '286 patent.

55. Upon information and belief, a reasonable Patent Examiner would have considered the '145 patent important to the patentability of the claims in the application leading to the Falotico '286 patent.

56. Upon information and belief, one or more of the Applicants knew of the '145 patent and its materiality during prosecution of the application leading to the Falotico '286 patent. For example, upon information and belief, one or more of the Applicants knew of the '145 patent via the on-going licensing relationship between Cordis and the assignee of the '145 patent.

57. Despite having knowledge that the '145 patent was relevant and material to the prosecution of the application leading to the Falotico '286 patent, one or more of the Applicants nevertheless failed to disclose the '145 patent to the PTO during prosecution of that application. This failure to disclose the highly material '145 patent was motivated by, and accomplished with, the intent to deceive the PTO into granting the Falotico '286 patent.

58. As another example of the inequitable conduct before the PTO that renders the Falotico '286 patent unenforceable, as part of the filing and prosecution of the applications leading to the Falotico '286 patent, one or more of the Applicants failed to disclose that (a) none of the named inventors first discovered the use of the claimed "rapamycin, or a macrocyclic

lactone analog hereof" to inhibit neointimal proliferation and/or restenosis (including delivery via a stent), but instead learned this information from another source(s) and (b) none of the originally-named inventors were the first to conceive and/or reduce to practice the claims pursued in the applications leading to the Falotico '286 patent. For example, according to Cordis' supplemental interrogatory responses dated July 24, 2008, Dr. Robert Falotico (not an originally-named inventor) learned of rapamycin, and its ability to inhibit restenosis, before any of the other named inventors and he learned that information from an unidentified third-party source. Upon information and belief, one or more of the Applicants failed to disclose this information with the intent to deceive the PTO into granting the Falotico '286 patent.

59. Upon information and belief, a reasonable Patent Examiner would have considered the information described in the preceding paragraph important to the patentability of the claims in the applications leading to the Falotico '286 patent.

60. Upon information and belief, one or more of the Applicants knew of this information and its materiality during prosecution of the applications leading to the Falotico '286 patent and nevertheless failed to cite it to the PTO. For example, despite knowing this information, none of the Applicants disclosed this information to the PTO, or informed the PTO of known inventorship errors, despite repeated opportunities to do so over many years. Moreover, when inventorship changes were made in 2007, the aforementioned material information still was not disclosed to the PTO. This failure to disclose highly material information was motivated by, and accomplished with, the intent to deceive the PTO into granting the Falotico '286 patent.

61. As another example of the inequitable conduct before the PTO that renders the Falotico '286 patent unenforceable, as part of the filing and prosecution of the applications

leading to the Falotico '286 patent, one or more of the Applicants intentionally obscured, hid, or concealed material prior art patents, publications, and/or papers from other proceedings that refuted, or were inconsistent with, the patentability of the claims pursued in the applications leading to the Falotico '286 patent. Such material documents were obscured, hidden, or concealed by either improperly burying them in a massive list of mostly irrelevant or marginally relevant references or not disclosing them at all.

62. For instance, U.S. Patent No. 5,516,781 ("the '781 patent") was a prior art reference material to the patentability of the claims pursued in the applications leading to the Falotico '286 patent. Like the claims being pursued, the '781 patent discloses, *inter alia*, the delivery of rapamycin via a stent to inhibit neointimal proliferation and/or restenosis.

63. Upon information and belief, one or more of the Applicants knew of the '781 patent and its materiality during prosecution of the applications leading to the Falotico '286 patent. Indeed, upon information and belief, one or more of the Applicants were intimately familiar with the '781 patent and its material disclosure given that Cordis had a license under the '781 patent during the prosecution period.

64. The first application in the chain leading to the Falotico '286 patent is the '568 Application. Despite having detailed knowledge that the '781 patent was relevant and material to the prosecution of the '568 Application, one or more of the Applicants nevertheless failed to disclose the '781 patent to the PTO during prosecution of that application. This failure to disclose the highly material '781 patent was motivated by, and accomplished with, the intent to deceive the PTO into granting a patent based on '568 Application.

65. The second application in the chain leading to the Falotico '286 patent is the '117 Application. During prosecution of the '117 Application, one or more of the Applicants

submitted an Information Disclosure Statement (“IDS”) on or about June 4, 2001. The June 2001 IDS listed more than 80 U.S. and foreign patent references. Upon information and belief, one or more of the Applicants knew that many of the listed references were of minimal or no relevance. Notwithstanding the large size of the IDS disclosure, none of the Applicants identified the references of most significance or the pertinent portions of the listed references.

66. Additionally, the ’117 Application IDS listed nearly all of the cited references in increasing numerical order. However, at the very end of the lengthy list, one or more of the Applicants buried a few U.S. patents out of order. These “out-of-order” patents included the ’781 patent as well as certain other material prior art references. On information and belief, one or more of the Applicants knowingly and intentionally buried the ’781 patent, and certain other material references, at the end of the list to obscure those references from the Patent Examiner. Upon information and belief, the out-of-order listing of the ’781 patent was not accidental given that (among other things) one or more of the Applicants were intimately aware of the ’781 patent, and its materiality, long before preparing the IDS (e.g., given Cordis’ long-standing license under the ’781 patent as of the June 2001 IDS date).

67. The aforementioned conduct in connection with ’117 Application was motivated by, and accomplished with, the intent to deceive the PTO into granting a patent based on the ’117 Application. Ultimately, the Patent Examiner allowed claims substantially similar to, if not broader than, the claims of the Falotico ’286 patent without raising any rejections based on the ’781 patent.

68. The third application in the chain leading to the Falotico ’286 patent is the ’328 Application. During prosecution of the 328 Application, one or more of the Applicants submitted an Information Disclosure Statement (“IDS”) on or about April 7, 2003. The April 2003 IDS

listed more than 90 U.S. and foreign patent references and nearly 30 publications. Upon information and belief, one or more of the Applicants knew that many of the listed references were of minimal or no relevance. Notwithstanding the large size of the IDS disclosure, none of the Applicants identified the references of most significance or the pertinent portions of the listed references.

69. Additionally, the '328 Application IDS listed nearly all of the cited references in increasing numerical order. However, like the '116 Application, at the very end of the lengthy list, one or more of the Applicants buried a few U.S. patents out of order. These "out-of-order" patents included the '781 patent as well as certain other material prior art references. On information and belief, one or more of the Applicants knowingly and intentionally buried the '781 patent, and certain other material references, at the end of the list to obscure those references from the Patent Examiner.

70. Upon information and belief, the out-of-order listing of the '781 patent in the April 2003 IDS was not accidental, particularly given that one or more of the Applicants were intimately aware of the '781 patent, and its materiality, long before preparing the IDS (e.g., given Cordis' long-standing license under the '781 patent as of the April 2003 IDS date). Moreover, the Applicants had nearly two years to correct the erroneously ordered IDS from the '116 Application, but intentionally did not do so in order to obscure the '781 patent and other material references.

71. The aforementioned conduct in connection with '328 Application was motivated by, and accomplished with, the intent to deceive the PTO into granting a patent based on the '328 Application. Ultimately, the Patent Examiner allowed claims substantially similar to, if not

broader than, the claims of the Falotico '286 patent without raising any rejections based on the '781 patent.

72. In the subsequent applications leading to the Falotico '286 patent, one or more of the Applicants listed more than 900 references – totaling approximately 19,000 pages – in IDSs. The listed references included over 500 patents and printed publications as well as select papers from various proceedings. Upon information and belief, one or more of the Applicants knew that the vast majority of the approximately 19,000 pages were of minimal or no relevance. Notwithstanding the large size of the IDS disclosures, none of the Applicants identified the references of most significance or the pertinent portions of the listed references.

73. Further, the Patent Examiner responsible (at least in part) for the '568, '117, and '328 Applications was the same Patent Examiner responsible for the subsequent applications leading to the Falotico '286 patent. One or more of the Applicants knew that it would be impossible for the Patent Examiner to effectively analyze 19,000 pages to uncover material prior art and/or papers that contradicted the pending claims. They also knew that, based on their prior inequitable conduct, the same Patent Examiner had already allowed claims that had essentially the same or broader scope. Having already obtained essentially the same or broader claims from the same Patent Examiner, one or more of the Applicants knew that the Patent Examiner likely would not raise prior art rejections against narrower or like claims. Only then did the Applicants finally list (a) the '781 patent in numerical order in the IDS submissions (albeit as part of a massive list of approximately 900 references) and (b) a large number of additional patents and papers from other proceedings.

74. During the prosecution of the applications leading to the Falotico '286 patent, none of the Applicants informed the Patent Examiner of the materiality of the 781 patent or

Cordis' licensing relationship with respect to that patent. Nor did they inform the Patent Examiner of any prior patents or papers from other proceedings that refuted, or were inconsistent with, the patentability of the pending claims.

75. The aforementioned conduct in connection with the applications leading to the Falotico '286 patent was motivated by, and accomplished with, the intent to deceive the PTO into granting the Falotico '286 patent. In accordance with the Applicants' improper conduct, the Patent Examiner ultimately allowed the Falotico '286 patent without raising any rejections based on the prior art patents or proceeding papers generally, or the '781 patent specifically (only obviousness-type double patenting rejections were raised).

76. In sum, as shown by the examples above, one or more of the Applicants knowingly and intentionally sought to deceive the PTO by obscuring, hiding, or concealing highly material prior art patents, publications, and/or papers from other proceedings that refuted, or were inconsistent with, the patentability of the claims pursued in the applications leading to the Falotico '286 patent. As noted previously, BSC believes that additional examples likely will have evidentiary support after a reasonable opportunity for further investigation and discovery. This intentional conduct, which occurred throughout the prosecution of the applications leading to the Falotico '286 patent, renders the Falotico '286 patent unenforceable.

77. As another example of the inequitable conduct before the PTO that renders the Falotico '286 patent unenforceable, as part of the filing and prosecution of the application leading to the Falotico '286 patent, one or more of the Applicants failed to disclose material information from related patent prosecution.

78. For instance, on May 7, 2001, Cordis filed U.S. Patent Application Serial No. 09/850,482 ("the '482 Application"). The '482 Application is related to the Falotico '286 patent.

It claims priority, at least in part, to the '568 Application, which is in the chain of applications leading to the Falotico '286 patent. Further, the '482 Application and the Falotico '286 patent share named inventors. The Patent Examiner responsible for the '482 Application was different than the Patent Examiner responsible for the application leading to the Falotico '286 patent.

79. In the '482 Application, Cordis sought claims directed to a stent with, among other things, a polymer matrix on its outer surface that incorporates rapamycin. The Patent Examiner for the '482 Application twice rejected the rapamycin claims as obvious in view of, among other things, (a) the '781 patent because it specifically teaches the use and delivery of rapamycin via a stent to treat restenosis and (b) the well-known properties of rapamycin:

Ragheb et al. as modified by Chudzik et al. disclose the invention with the exception of the anti-proliferative compound of rapamycin. Although, Ragheb et al. discuss using the invention for preventing restenosis such as from chronic remodeling and neointimal hyperplasia, reducing proliferation, and other needs for anti-proliferative therapy, the drug rapamycin is not explicitly recited.

On the other hand, [the '781 patent] teaches of rapamycin as an anti-proliferative for use via stents. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Ragheb et al. to include rapamycin for the purpose of utilizing its superior qualities as an anti-proliferative as taught by [the '781 patent]. Furthermore, rapamycin is known for its antiinflammatory and anti-proliferative properties, as seen in the Appendix. Therefore, it would be within the scope of the invention to include rapamycin as an obvious choice of antiproliferatives.

(2/7/03 Office Action from '482 Application at ¶ 5; *see also* 10/17/02 Office Action from '482 Application at ¶ 6 ("Ragheb et al. disclose the invention with the exception of the antiproliferative compound of rapamycin that is incorporated in a polymer matrix onto the outer surface of the [stent] bands On the other hand, [the '781 patent] teach[es] of rapamycin as an anti-proliferative. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Ragheb et al. to include rapamycin for the purpose of utilizing its

superior qualities as an anti-proliferative as taught by [the '781 patent]."). Cordis was unable to overcome these rejections.

80. Upon information and belief, a reasonable Patent Examiner would have considered the '482 Application prosecution (including any discussions of the '781 patent) important to the patentability of the claims in the application leading to the Falotico '286 patent.

81. Upon information and belief, one or more of the Applicants knew of the '482 Application prosecution and its materiality during prosecution of the application leading to the Falotico '286 patent and nevertheless failed to cite it to the PTO. This failure to disclose highly material information from the '482 Application prosecution was motivated by, and accomplished with, the intent to deceive the PTO into granting the Falotico '286 patent.

82. These examples of intentional and deceptive acts, as described in the above paragraphs constitute inequitable conduct such that the Falotico '286 patent is unenforceable.

PRAYER FOR RELIEF

WHEREFORE, BSC prays that this Court enter judgment as follows, ordering that:

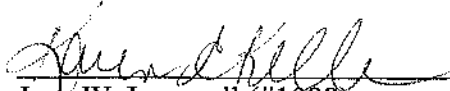
- (a) Each and every claim of U.S. Patent No. 7,217,286 is invalid and unenforceable due to inequitable conduct before the PTO;
- (b) Plaintiffs are not liable for directly, contributorily or inducing infringement of any claim of U.S. Patent No. 7,217,286;
- (c) Defendants and their officers, agents, employees, representatives, counsel and all persons in active concert or participation with any of them, directly or indirectly, be enjoined from threatening or charging infringement of, or instituting any action for infringement of U.S. Patent No. 7,217,286 against Plaintiffs, its suppliers, customers, distributors or users of its products;
- (d) Defendants pay to Plaintiffs the costs and reasonable attorney's fees incurred by Plaintiffs in this action; and
- (e) Plaintiffs be granted such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues so triable.

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TAYLOR, LLP

Dated: December 23, 2008



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EXHIBIT A



US007217286B2

(12) **United States Patent**
Falotico et al.

(10) Patent No.: **US 7,217,286 B2**(45) Date of Patent: ***May 15, 2007**

(54) **LOCAL DELIVERY OF RAPAMYCIN FOR TREATMENT OF PROLIFERATIVE SEQUELAE ASSOCIATED WITH PTCA PROCEDURES, INCLUDING DELIVERY USING A MODIFIED STENT**

(58) Field of Classification Search 623/1.45-1.48;
427/2.1-2.31
See application file for complete search history.

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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Primary Examiner—Suzette Gherbi

(74) Attorney, Agent, or Firm—Woodcock Washburn LLP

(57) ABSTRACT

Methods of preparing intravascular stents with a polymeric coating containing macrocyclic lactone (such as rapamycin or its analogs), stents and stent graphs with such coatings, and methods of treating a coronary artery with such devices. The macrocyclic lactone-based polymeric coating facilitates the performance of such devices in inhibiting restenosis.

(65) Prior Publication Data
US 2007/0021825 A1 Jan. 25, 2007

Related U.S. Application Data

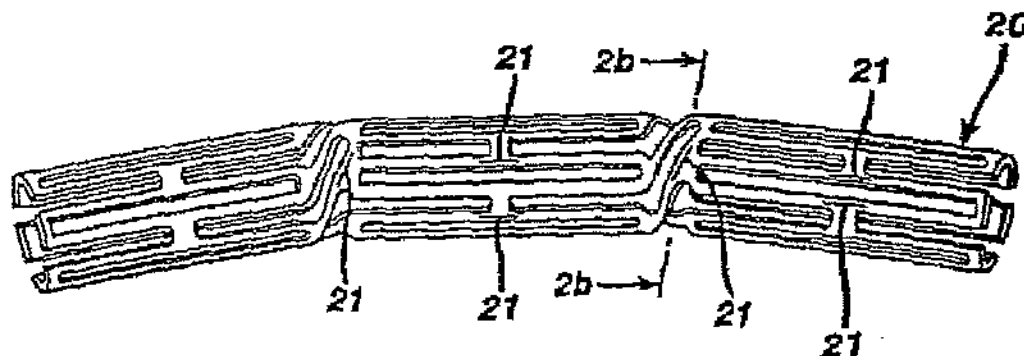
(63) Continuation of application No. 10/951,385, filed on Sep. 28, 2004, which is a continuation of application No. 10/408,328, filed on Apr. 7, 2003, now Pat. No. 6,808,536, which is a continuation of application No. 09/874,117, filed on Jan. 4, 2001, now Pat. No. 6,585,764, which is a continuation of application No. 09/061,568, filed on Apr. 16, 1998, now Pat. No. 6,273,913.

(60) Provisional application No. 60/044,692, filed on Apr. 18, 1997.

(51) Int. Cl.
A61F 2/06 (2006.01)

(52) U.S. Cl. 623/1.42

5 Claims, 2 Drawing Sheets



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EXHIBIT B

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CORDIS CORPORATION)	
)	
Plaintiff,)	
)	Civil Action No.
vs.)	
)	COMPLAINT AND DEMAND
)	FOR JURY TRIAL
ABBOTT LABORATORIES.,)	
)	<i>Document Filed Electronically</i>
Defendant.)	

Plaintiff Cordis Corporation, by its attorneys, alleges as follows:

THE PARTIES

1. Plaintiff Cordis Corporation ("Cordis"), 33 Technology Drive, Warren, New Jersey, is a Florida corporation with a principal place of business in Warren, New Jersey. Cordis also has facilities in Clark, New Jersey. Cordis is a pioneer in developing invasive

treatments for vascular disease, including the CYPHER[®] drug-eluting stent, a drug/device combination for the treatment of coronary artery disease.

2. Upon information and belief, Defendant Abbott Laboratories ("Abbott"), 100 Abbott Park Road, North Chicago, IL 60064, is an Illinois corporation with a principal place of business in Illinois.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over Cordis's patent infringement claims under 28 U.S.C. § 1331 and 1338(a).

4. This Court has personal jurisdiction over Abbott. On information and belief, Abbott has systematic and continuous contacts in this judicial District, regularly transacts business within this judicial District, and regularly avails itself of the benefits of this judicial District. For example, Abbott is registered to do business in New Jersey, and has facilities located in this District, including in East Windsor, Cranbury, South Brunswick, Edison, Whippany, and Parsippany, New Jersey. On information and belief, Abbott also has numerous employees in this District, derives substantial revenues from its business operations and sales in this district, and pays taxes in New Jersey based on revenue generated in this District. On information and belief, Abbott also sells and distributes medical devices in this District, including vascular devices.

5. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

FACTUAL ALLEGATIONS

6. Abbott is the manufacturer of a drug-eluting stent named XIENCE V Everolimus Eluting Coronary Stent System ("XIENCE V stent"). Abbott has manufactured

thousands of XIENCE V products in the United States for sale in Europe and Asia. Abbott launched the XIENCE V stent in Europe and the Asia Pacific regions in 2006.

7. On May 15, 2007, the United States Patent and Trademark Office ("USPTO") duly and legally issued United States Patent No. 7,217,286, entitled "Local Delivery of Rapamycin For Treatment of Proliferative Sequelae Associated With PTCA Procedures, Including Delivery Using a Modified Stent" (the "'286 patent"). The '286 patent issued to Robert Falotico and Gerard H. Llanos, and is assigned to Cordis. Cordis holds all right, title and interest in and to the '286 patent.

8. Abbott has been and is performing acts covered by the claims of the '286 patent, including making and/or using the XIENCE V stent in the United States for sale in Europe and Asia.

9. At present, there are only two companies marketing in the United States drug eluting stents – Cordis and Boston Scientific Corporation. Abbott has publicly announced that it plans to seek approval from the United States Food and Drug Administration in the second quarter of 2007 to sell the XIENCE V stent in the United States. Abbott has also publicly announced that, assuming it receives regulatory approval, it plans to launch the XIENCE V stent in the United States in the first half of 2008. Upon its launch in the United States, the XIENCE V stent will compete directly with Cordis's CYPHER stent, reducing Cordis's market share and causing irreparable harm to Cordis.

COUNT I: INFRINGEMENT OF THE '286 PATENT

10. Cordis realleges paragraphs 1-9 above as if fully set forth herein.

11. Abbott is infringing the '286 patent in violation of 35 U.S.C. § 271, including by making and/or using the XIENCE V stent in the United States.

12. Abbott had and has actual notice of the '286 patent, and is infringing the '286 patent with knowledge of Cordis's patent rights. Abbott's actions are willful and deliberate.

PRAYER FOR RELIEF

WHEREFORE, Cordis prays for the following relief against Abbott:

1. For judgment in favor of Cordis that Abbott is infringing Cordis's patent;
2. For a preliminary and permanent injunction pursuant to 35 U.S.C. § 283 prohibiting Abbott from making, using, selling, or offering for sale the infringing products in the United States;
3. For an award of damages for Abbott's infringement of Cordis's patent, together with interest (both pre-and post-judgment), costs, and disbursements as fixed by this Court under 35 U.S.C. § 284;
4. For a determination that Abbott's infringement is willful, and an award of treble the amount of damages and losses sustained by Cordis as a result of Abbott's infringement, under 35 U.S.C. § 284;
5. For a determination that this is an exceptional case within the meaning of 35 U.S.C. § 285, and an award to Cordis of its reasonable attorneys' fees; and
6. For such other and further relief in law or in equity to which Cordis may be justly entitled.

DEMAND FOR JURY TRIAL

Cordis demands a trial by jury of any and all issues triable of right before a jury.

Dated: May 15, 2007.

By:

s/Donald A. Robinson

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